REMARKS

I. Status of the Application

Claims 1-23, 25-35, 37-51 and 53-72 are pending in the application. Claims 1-23, 25-33, 37, 45-50, 55 and 56 are withdrawn. Claims 34, 35, 38-44 and 58-66 are rejected under 35 U.S.C. § 103(a) as being unpatentable over European Patent No. 0 099 167 to Yapp ("Yapp"). Claims 51, 53, 54, 57 and 67-72 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,571,203 to Masini ("Masini").

Applicants respectfully request reconsideration of the application in view of the following remarks.

II. Claims 34, 35, 38-44 and 58-66 Are Patentable Over Yapp

Claims 34, 35, 38-44, and 58-66 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Yapp. This rejection is respectfully traversed.

Yap fails to disclose or make obvious a fastening element having a pin extending from a supporting element, with the pin having a longitudinal axis that extends at an angle of between about 125° and about 145° with respect to the bottom surface of the supporting element, as required by independent claim 34. Yapp also fails to disclose or make obvious a fastening element with a pin extending from a first side of a support element at an angle greater than 90° with the first side, as required by independent claim 59.

The Office Action restates the previous rejection over Yapp, asserting that the required angle would have been obvious to one skilled in the art, stating "that where the general conditions of a claim are disclosed in the prior art, **discovering the optimum or workable ranges** involves only routine skill in the art."

Applicant respectfully points out that this statement actually provides support for the Applicant's position that the claimed invention is not obvious in view of the teachings of Yapp. Not only is **the claimed angle not within an optimum range based on the teachings of Yapp, it is not even within the workable range based on the teachings of Yapp.**

As acknowledged in the Office Action, the angle between the longitudinal axis of the pin and the bottom surface of the plate is 90° in Yapp. Shaft 13 extends linearly from the neck 16 through the femur and emerges from the lateral cortex 19 **just below the trochanter**. (Yapp, page 4, lines 14-17). Bolt 28 is threaded into shaft 13 to hold it in **this desired location**.

> "A broad, shallow depression 46 is rounded from the exterior of the lateral cortex 19 **just below the trochanter 38** to provide food seating and ingrowth into the porous interior surface of a grommet or washer 47", through which bolt 28 extends." (Yapp, page 4, lines 32-34; emphasis added.)

Thus, the optimum and workable range for Yapp is that which would extend shaft 13 such that it would extend to the point just below the trochanter 38.

If the angle between the pin and the plate of Yapp were greater than 90°, let alone between about 125° and about 140°, the shaft 13 of Yapp would extend further down into the femur, and would not exit the femur in the **desired position**, that is, "just **below the trochanter** 38."

Consequently, it can be seen that Yapp actually teaches away from the required angle of between about 125° and about 145°, as required by independent claim 34. Contrary to the assertion in the Office Action, the required angle of greater than 90° and the required range of between about 125° and about 145° would be neither "optimum or workable ranges" as applied to Yapp. An angle greater than 90°, and especially one between about 125° and about 145°, would simply not work in the fastener of Yapp. Such a large angle would not allow the bolt 28 and washer 47 to be located in the desired position just below the trochanter.

The Office Action further states in response to the arguments presented in the previously filed response, the test for obviousness is "what the references as a whole make obvious to one of ordinary skill in the pertinent art...would merely involve routine skill in the art to determine." Applicant respectfully submits that one skilled in the art using routine skill would not be motivated or have any suggestion to include such limitations in the device of Yapp.

Since, as discussed above, one skilled in the art would be taught away from an angle greater than 90°, let alone an angle between about 125° and about 140°, modifying Yapp to include such a limitation would clearly not be routine. "A prior art reference must be considered in its entirety... including portions that would lead away from the claimed invention." W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983); MPEP § 2141.02.

Accordingly, the rejection is improper and should be withdrawn.

III. Claims 51, 53, 54, 57 and 67-72 Are Patentable Over Masini

Claims 51, 53, 54, 57 and 67-72 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Masini. This rejection is respectfully traversed.

Masini fails to disclose or make obvious a method for fastening an implant including the step of forming an abutment surface that extends approximately at right angles to the load axis of the joint, as required by independent claims 51 and 67.

The Office Action states on page 4 that "Masini discloses a method of sawing a femur on a cut line 230 to create an abutment surface that extends at right angles to a load axis of a joint (see Figs. 2-4 and 6 and col. 6, lines 35-65)."

Applicant respectfully points out that the abutment surface of Masini is not at a right angle with respect to the load axis of this joint. The abutment surface of Masini is at a right angle to the longitudinal axis 234 of the femur, which **is not** the load axis of the joint. The longitudinal axis 234 of the femur is actually at an angle with respect to the load axis of the joint.

As can be seen in Fig. 1A of the present invention, and described at page 7, line 29 through page 8, line 2, the load axis is a straight line drawn through the center of the hip head and the intercondylar space of the knee. The load axis is not parallel with the longitudinal axis of the femur. Rather, it usually includes an angle between 6° and 12°.

Consequently, since the abutment surface of Masini is at a right angle to the longitudinal axis 234 of the femur, it cannot be at a right angle to the load axis of the joint.

Further, as noted in the Office Action, Masini fails to disclose or make obvious a pin driven into a bone at an angle of between about 125° and about 145° with respect to the abutment surface, as required by independent claim 51. Masini also fails to disclose or make cementing a fastening element into a hole with a pin extending from a first side of a support element at an angle greater than 90° with the first side, as required by independent claim 67.

The Office Action acknowledges that Masini does not disclose an angle between the longitudinal axis of the pin and the bottom surface of the supporting element of between about 125° and about 145°, but asserts that the required angle would have been obvious to one skilled in the art, stating that discovering the optimum or workable ranges involves only routine skill in the art.

As noted above with respect to Yapp, not only is **the claimed angle not within an optimum range based on the teachings of Masini, it is not even within the workable range based on the teachings of Masini.**

If the angle between the pin 312 and the support element 226 were greater than 90°, and especially if it were between about 125° and about 145°, the fins 310 on pin 312 would extend into the cortex. Masini **expressly teaches away** from such a result. Specifically, Masini states that it is important to "**ensure that** ... **the fins** remain within the softer candellous bone, and **do not invade the cortex**, which might crack under the forces associated with installation." (col. 6, lines 6-10; emphasis added).

Consequently, it can be seen that Masini actually **teaches away** from the required angle of greater than 90° and the required range of between about 125° and about 145°. An angle greater than 90°, and especially one between about 125° and about 145°, would simply not work in the fastener of Masini. "A prior art reference must be considered in its entirety... including portions that would lead away from the claimed invention." W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983); MPEP § 2141.02.

Additionally, there is no motivation or suggestion for one skilled in the art to modify Masini to provide a coupling element offset with respect to the longitudinal axis of the pin, as required by claims 57 and 67. There is simply no *prima facie* case of obviousness presented in the Office Action to modify this relationship.

With respect to claim 53, Applicant respectfully points out that Masini does not disclose or make obvious a pin driven into a bone such that a longitudinal axis of the pin extends approximately parallel to the longitudinal axis of the neck. Rather, the axis of the pin of Masini extends parallel to the longitudinal axis of the femur itself.

Accordingly, for these reasons the rejection is improper and should be withdrawn.

IV. CONCLUSION

Reconsideration and allowance of all the pending claims is respectfully requested. If a telephone conversation with Applicant's attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 720-9600.

The Commissioner is hereby authorized to charge any additional fees or credit overpayment to Deposit Account No. 19-0733.

Respectfully submitted,

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